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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,879	05/22/2001	Kazuya Katagai	MUR-026-USA-	8324

7590 05/19/2003

601 Pennsylvania Avenue NW  
Suite 900  
South Building  
Washington, DC 20004

[REDACTED] EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	10

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/831,879	KATAGAI ET AL.
Examiner	Art Unit	
Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11 March 2003.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-12 and 14-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-12 and 14-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application***

Applicant's election without traverse of Group I, claims 1-12 and 14-17 in Paper No. 8 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### **Claims are rejected under 35 U.S.C. 102(b) as being anticipated by**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-4 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-325149 in view of Obayashi et al (4,880,888).**

JP teaches an external preparation containing an active agent (pridinol), water-soluble polymers (polyacrylic acid polymer), polyhydric alcohols (glycerol/ benzyl alcohol blend), and antioxidant (sodium hydrogen sulfite). Crosslinking agents such as organic acid or salt of an organic acid are included in the composition. See Detailed Description in its entirety). The instant ratio of drug to polymer is taught in the examples.

JP does not specify the polyfunctional epoxy compound crosslinking agents.

Obayashi et al teach a water-absorbent resin such as polyacrylic acids.

Crosslinking agents taught for the water-soluble resins are agents that react with carboxyl groups of the polymer are diglycidyl ether compounds. See column 4, lines 59-68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings JP and Obayashi et al and use the instant polyfunctional epoxy compound as the crosslinking agent. One would be motivated to do so since Obayashi teaches the instant crosslinking agents react with carboxyl groups of the carboxylic acid polymers. Therefore one of ordinary skill in the art would expect similar results since JP teaches the use of polyacrylic acid, which is a carboxylic acid polymer.

**Claims 6-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-325149 in view of Obayashi et al (4,880,888) in further view of Sage et al (5,540,669).**

As set forth above, JP teaches an external adhesive preparation containing a drug, polymers, polyhydric alcohols, crosslinking agents, and antioxidants (sodium hydrogen sulfite). Obayashi teaches instant crosslinking agents that react with polyacrylic acid polymers.

The references do not teach a mixture of lidocaine and epinephrine.

Sage et al teach an iontophoretic drug delivery wherein the electrodes have reservoirs containing 5-15% lidocaine and 0.03-3% epinephrine. See column 4, lines 9-15. Sage discloses that there are two types of transdermal delivery: active and passive. Active transdermal devices have disadvantages such as pain associated with the devices, therefore the combined use of the drugs alleviates this problem. See column 1, lines 25-64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the teachings of Sage and incorporate a lidocaine and epinephrine drug combination since Sage teaches the state of the art at the time the invention was made, demonstrating that the instant drug combination is known and used in the transdermal art. Furthermore, one would be motivated to use the instant combination to alleviate the disadvantages associated with active transdermal drug delivery as taught by Sage et al.

**Claims 1-5 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al (5,725,874).**

Oda et al teach an external preparation that contains .001-20% of a drug, 1-30% of a water-soluble polymer such as polyacrylic acid, isobutylenemaleic anhydride

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copolymer, water, and a polyhydric alcohol. See column 3. The base may include a crosslinking agent such as a polyfunctional epoxy compound. See column 4, lines 13-30.

The reference does not exemplify a composition containing the crosslinking agent.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to include the crosslinking agent in the composition. One would be motivated to do so with the expectation of similar results since Oda clearly suggests the incorporation of crosslinking agents.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

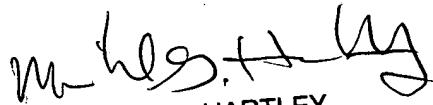
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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~~MA~~  
May 14, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER